UNITED STATES PATENT AND TRADEMARK OFFICE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

Paper No. 27

Application Number: 09/207,161
Filing Date: December 07, 1998
Appellant(s): HILLMAN ET AL.

Richard C. Ekstrom
For Appellant

EXAMINER'S ANSWER

This is in response to appellant's brief on appeal filed May 31, 2001 (Paper #24).

(1) Real Party in Interest

A statement identifying the real party in interest is contained in the brief.

(2) Related Appeals and Interferences

A statement identifying the related appeals and interferences which will directly affect or be directly affected by or have a bearing on the decision in the pending appeal is contained in the brief.

(3) Status of Claims

The statement of the status of the claims contained in the brief is incorrect. A correct statement of the status of the claims is as follows:

This appeal involves claims 1 and 11.

Claims 12-20 have been withdrawn from consideration as not directed to the elected invention.

Claims 2-10 have been canceled.

(4) Status of Amendments After Final

The appellant's statement of the status of amendments after final rejection contained in the brief is correct. As noted in the Interview held July 10, 2001, the third after-final amendment has been entered.

(5) Summary of Invention

The summary of invention contained in the brief is correct.

(6) Issues

The appellant's statement of the issues in the brief is substantially correct. The changes are as follows:

Whether Claims 1 and 11 lack utility under 35 USC 101.

Whether Claims 1 and 11 lack enablement under 35 USC 112, first paragraph.

(7) Grouping of Claims

Appellant's brief includes a statement that claims 1 and 11 do not stand or fall together and provides reasons as set forth in 37 CFR 1.192(c)(7) and (c)(8).

(8) Claims Appealed

The copy of the appealed claims contained in the Appendix to the brief is correct. However, as noted in the Interview held July 10, 2001, the comma at the end of Claim 1 will be changed to a period by Appellants *after* the BPAI have rendered their decision on the appeal.

(9) Prior Art of Record

No prior art is relied upon by the examiner in the rejection of the claims under appeal.

(10) Grounds of Rejection

The following ground(s) of rejection are applicable to the appealed claims:

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1 and 11 stand rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility. The specification states that the IMP-2 protein is presumed to be a type II integral membrane protein and provides a method to confirm this presumption (page 50, line 6). The type II integral membrane proteins are stated to have an amino terminal cytoplasmic domain that is typically small and generally lacks enzymatic activity and are not directly involved in transmembrane signaling. The carboxy terminal extracellular domain typically comprises the active portion of the protein such as enzymatic or receptor binding domain activity (para. bridging pages 1-2). At page 2, para. 1, the specification compares IMP-2 to the mouse multigene E24 failing of type II integral membrane proteins and discusses expression patterns of mouse *Itm2* gene. At page 14, paras 104, the specification teaches the biochemical characteristics of IMP-2. In no place does the specification teach the function of IMP-2 protein. The IMP-2 protein sequence is deduced from the cDNA sequence and the protein itself has not been produced.

The specification teaches that IMP-2 can be used to treat liver diseases including liver tumors (page 4, line 29) and to treat a variety of tumors (page 5, line 3). IMP-2 is also taught to

be useful for the diagnosis, prevention, or treatment of diseases associated with abnormal liver tissue including tumors. At page 28, para. 1 the specification teaches that IMP-2 or fragments or derivatives thereof may be administered to a subject to treat disorders associated with abnormal liver functions as well as a variety of tumors. Conditions and diseases to be treated include liver tumors, primary biliary cirrhosis, lung, brain, prostate, breast, and bladder tumors.

The asserted utilities set forth in the specification are considered to be general utilities that would be applicable to the broad class of the invention. Utilities that require or constitute carrying out further research to identify or reasonably confirm a "real world" context of use are not substantial utilities. Because Applicant has not disclosed any specific and substantial utility for the claimed invention, credibility will not be assessed.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 1 and 11 stand rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific or substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

(11) Response to Argument

Appellants arguments begin at page 16 (Issue 3). Appellants discuss the expression pattern of the claimed polypeptide and state that this expression pattern provides numerous practical, beneficial uses in toxicology testing, drug development, and the diagnosis of disease. Appellants do not discuss what toxicology testing that the expression pattern will aid in

determining, what drug will be developed by knowing this expression pattern or what disease will be diagnosed by knowing this expression pattern. Therefore, this argument is not persuasive.

Appellants discuss case law at page 17 and conclude that the rejection fails to demonstrate either that the Appellants assertions of utility are legally insufficient or that a person or ordinary skill in the art would reasonably doubt that they could be achieved. As noted above, there is no specific toxicology testing stated, no specific drug to be developed, and no specific disease to be diagnosed. Therefore, Appellants assertions of utility do no meet the legal standards of 35 USC 101 and no person of ordinary skill in the art could guess what toxicology test, drug to be developed, or disease to be diagnosed would be based on the expression pattern of the claimed polypeptide.

At pages 18-32, Appellants assert that the Guidelines are themselves inconsistent with the law. It is noted that Appellants do not assert that the Examiner has mis-applied the Guidlelines, but that the Guidelines are themselves flawed. The Examiner will only address parts of this critique as it applies to the instant invention and rejection.

Appellants assert that the use of expression profiling has a well-established utility as tools for toxicology testing, drug discovery, and diagnosis of disease (IA at page 18). As noted above, what toxicology testing that the expression pattern will aid in determining, what drug will be developed by knowing this expression pattern, or what disease will be diagnosed by knowing this expression pattern is not provided. Appellants are asking others to use their polypeptide to determine what it is useful for – the toxicology of nicotine? the development of drugs to treat Alzheimer's? the diagnosis of breast cancer? for example. Therefore, this argument is not persuasive.

Appellants assert that the use of IMP-2 proteins for toxicology testing, drug discovery, and diagnosis of disease because practical, beneficial use and not functionality is at the core of the utility requirement (IB1 at page 22). Appellants assert that the claimed inventions is known to be

useful, for example, in toxicology test to determine whether a drug or toxin changes the expression pattern of the protein, or to determine whether a specific medical condition affects the expression of the protein, or serve as a marker for or to assess the stage of a particular disease or condition. Appellants do not provide any information regarding what drug or toxin will affect the expression pattern of the protein or what it may mean. Appellants do not provide any information as to any medical condition that may affect the expression pattern of the protein or what it may mean. Appellants do not provide any information as to what disease or condition the protein could be a marker for. As noted above, what toxicology testing that the expression pattern will aid in determining, what drug will be developed by knowing this expression pattern, or what disease will be diagnosed by knowing this expression pattern is not provided. Appellants are asking others to use their polypeptide to determine what the polypeptide is useful for – the toxicology of nicotine? the development of drugs to treat Alzheimer's? the diagnosis of breast cancer? for example. Therefore, this argument is not persuasive.

Appellants assert (IB2 at page 23) that the invention is a member of a broad class of DNA in general which include those sequences having utility. Therefore Appellants conclude that the generally utility for the class is sufficient for the claimed species and that all isolated and purified polynucleotide and polypeptide sequences which are expressable can be and are used in a real-world context as tools for toxicology testing such as for drug discovery purposes. This argument is not persuasive for all of the reasons provided above.

Appellants argue (IC at page 26) that the use of the protein as a research tool is a substantial utility and cite such uses as diagnosis of disease for example. Again, no disease is stated that can be diagnosed by knowing the expression pattern of the IMP-2 protein. Therefore, this argument is not persuasive because one skilled in the art would have to determine for themselves which disease could be diagnosed by knowing the expression pattern of the claimed protein.

Appellants assert (ID at page 27) that the sale of the sequences of the claimed polypeptide to databases is evidence of utility. This argument is noted but this deals with nonfunctional descriptive material, that is, the sequences of bases having no known function. While the arguments deal with the database, the database structure may or may not be patentable, the data in the database is not patentable. Since the data is nonfunctional and descriptive material, the arguments are moot and not on point.

Appellants assert that the Examiner failed to demonstrate that a person of ordinary skill in the art would reasonable doubt the utility of the claimed invention.(II at page 28). All of these arguments have been addressed above. No specific, substantial, or well-established utility has been provided in the specification or by Appellants. Therefore, there is not utility provided for a person of ordinary skill to doubt.

Appellants again assert that the Guidelines misstate the law (III at pages 30). As noted above, the Examiner will not comment on the Guidelines.

For the above reasons, it is believed that the rejections should be sustained.

Respectfully submitted,

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